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Date: April 15, 2005By: J. Archer

Attorney Docket No. 100725-47 (KGB)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT : Jost SEIBLER et al
SERIAL NO. : To Be Assigned [This is a 371 of PCT/EP2003/011233]
CUSTOMER NO. : 27384
FILED : Herewith
FOR : SiRNA MEDIATED GENE SILENCING IN TRANSGENIC ANIMALS
ART UNIT : To Be Assigned
EXAMINER : To Be Assigned

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

SIR:

Pursuant to 37 CFR §§ 1.56, 1.97 and 1.98, Applicants respectfully request that the Examiner consider the references listed on the attached Form PTO-1449.

I. Timeliness, Fees and Certifications in lieu of Fees

☒ A. This information disclosure statement is being filed within three months of the filing date of the application, or within three months of entry into the national stage, or before the mailing of a first Office Action on the merits. Pursuant to 37 CFR § 1.97(b), consideration of this information disclosure statement does not require a fee or a statement under 37 CFR § 1.97(e). However, should the Assistant Commissioner determine that a fee

is, in fact, due, the Assistant Commissioner is hereby authorized to charge the fee to Deposit Account No. 14-1263.

☐ B. This information disclosure statement is being filed after the period in A above, but before the mailing of either a final action or a notice of allowance. Pursuant to 37 CFR § 1.97(c), consideration of this information disclosure statement requires a fee or a statement under 37 CFR § 1.97(e):

☐ 1. The Assistant Commissioner is hereby authorized to charge the fee set forth in 37 CFR § 1.17(p) to Deposit Account No. 14-1263.

☐ 2. Applicants hereby state that each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.

☐ 3. Applicants hereby state that no item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign patent application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 CFR § 1.56 more than three months prior to the filing of this information disclosure statement.

☐ C. This information disclosure statement is being filed after the period specified in B above, but on or before the payment of the issue fee. Pursuant to 37 CFR § 1.97(d), consideration of this information disclosure statement requires a petition, which Applicants hereby request, and payment of the petition fee, which is set forth in 37 CFR § 1.17(i), and which the Assistant Commissioner is hereby authorized to charge to Deposit Account No. 14-1263. Consideration of this information disclosure statement also requires a statement under 37 CFR § 1.97(e):

☐ 1. Applicants hereby state that each item of information contained in this information disclosure statement was cited in a communication from a foreign patent

office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.

☐ 2. Applicants hereby state that no item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign patent application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 CFR § 1.56 more than three months prior to the filing of this information disclosure statement.

II. Copies of Listed References

☐ A. Copies of all references listed on the attached Form PTO-1449 are being supplied. Copies of U.S. patents are not included pursuant to Pre-OG Notice dated July 11, 2003.

☐ B. Copies of all references listed on the attached Form PTO-1449 have already been supplied during the prosecution of prior application Serial No. ____, filed ____, from which the present application claims priority pursuant to 35 USC § 120. Therefore, pursuant to 37 CFR § 1.98(d), copies of the references listed on the attached Form PTO-1449 are not now being supplied.

☒ C. This application is a PCT national stage application, all references listed on the attached Form PTO-1449 were cited in the international search report, and the copies of the references listed on the attached Form PTO-1449 are in this national stage file. Therefore, copies of the references listed on the attached Form PTO-1449 are not now being supplied.

III. Concise Statement of Relevance

☐ A. All references listed on the attached Form PTO-1449 are in the English language, and, therefore, a concise statement of relevance is not required.

☐ B. All references listed on the attached Form PTO-1449 are referred to in the specification and/or were cited in the international search report, and a copy of that search report, which indicates the degree of relevance found by the Search Authority, is attached.

The Examiner will note that English language counterparts or Abstracts of non-English language references are also enclosed, as follows:

☐ C. All references listed on the attached Form PTO-1449 were cited in the search report issued by the _____ Patent Office, and an English-language version of that search report, which indicates the degree of relevance found by that Patent Office, is attached.

☒ D. This application is a PCT national stage application, all references listed on the attached Form PTO-1449 were cited in the international search report, and a copy of that search report, which indicates the degree of relevance found by the International Search Authority, is attached.

☐ E. All listed on the attached Form PTO 1449 were cited during the prosecution of the prior application indicated above under II.B.

IV. Additional Information

☒ A. In addition to the references listed on the attached Form PTO-1449, Applicants wish to bring to the attention of the Examiner the following abandoned or co-pending U.S. patent applications:

10/685,837 filed October 15, 2003

[Pursuant to 37 CFR § 1.98(a)(2)(iii), copies of these applications are not being submitted.]

☐ B. In addition of the references listed on the attached Form PTO-1449, Applicants wish to bring to the attention of the Examiner the information provided on the attached sheet.

Consideration of the foregoing in relation to this application is respectfully requested.

Respectfully submitted,

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT'S (Form PTO-1449)		Application Number		10/531347		
		Filing Date:		Herewith		
		First Named Inventor		Jost SEIBLER et al		
		Art Unit		To Be Assigned		
		Examiner Name:		To Be Assigned		
Sheet 1		of 2		Attorney Docket Number: 100725-47 (KGB)		
U.S. PATENT DOCUMENTS						
Examiner's Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
		Number-Kind Code ²				
	AA	US -				
FOREIGN PATENT DOCUMENTS						
Examiner's Initials*	Cite No.	Foreign Patent Document	Publication Date MM-DD-YYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ - Kind Code ⁵				
	AB	WO 03/057840	07-17-2003	Allele Biotechnology & Pharmac		
	AC					
NON PATENT LITERATURE DOCUMENTS						
Examiner's Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.				T ⁶
	AD	DEVROE E & SILVER P A; "retrovirus-delivered SiRNA"; BMC Technology, Biomed Central, London, August 28, 2002; pages 1-5 XP002225637				
	AE	BRUMMELKAMP T. R. et al: "Asystem for stable expressions of short interfering RNAs in mammalian cells"; American Association for the Advancement of Science, US; Vol. 296No. 5567 (2002), pages 550-553, XP002225638				
	AF	PAUL C. P et al: "Effective expression of small interfering RNA in human cells"; Nature Biotechnology, Nature Publishing US, Vol. 20, No. 5; May 2002, pages 505-508, XP001121006				
	AG	LOSTNER et al.; "Doxycycline-mediated quantitative and tissue-specific control of gene expression in transgenic mice", Proceedings of the National Academy of Sciences of USA, Vol. 93, No. 20, October 1996, Pages 10933-10938, P002110022				
	AH	BRONSON, SARA K. et al; "Single-copy transgenic mice with chosen-site integration"; Proceedings of the National Academy of Sciences of the United States; Vol. 93, No. 19; (1996), pages 9067-9072, XP002270939				
	AI	HASUWA H. et al.: "Small interfering RNA and gene silencing in transgenic mice and rats"; Febs Letters, Elseviere Science Publishers, Amsterdam, NL; Vol. 532, No. 1-2; December 4, 2002, pages 227-230, XP004395375				
EXAMINER SIGNATURE:				DATE CONSIDERED:		
<p>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²see Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴for Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.</p> <p>The collection of information is required by 37 CFR 1.197 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.</p> <p>If you need assistance in completing this form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.</p>						

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		Filing Date:	Herewith
		First Named Inventor	Jost SEIBLER et al
		Art Unit	To Be Assigned
		Examiner Name:	To Be Assigned
Sheet 2	of 2	Attorney Docket Number:	100725-47 (KGB)
NON PATENT LITERATURE DOCUMENTS CONTINUED			
Examiner's Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	AJ	KAWASAKI H. et al; "Short hairpin type of dsRNAs that are controlled by tRNA Val promoter significantly induce RNAI-mediated gene silencing in the cytoplasm of human cells"; Nucleic Acids Research, Oxford University Press, Surrey, GB; Vol. 31, No. 2, January 2003; pages 700-7007, XP002965487	
	AK	MATSUKURA, SHIRO et al; "Establishment of conditional vectors for hairpin siRNA knockdowns"; Nucleic Acids Research, England, August 1, 2003; Vol. 31, No. 15, pages 1-5, XP002270940	
	AL	VAN DE WETERING, MARC et al: "Specific inhibition of gene expression using a stably integrated, inducible small-interfering-RNA vector.", Embo Reports; Vol. 4, No. 6, June 2003; pages 609-618, XP002270941	
	AM	MERLINO G T, et al: "Accurate in-vitro transcriptional initiation of the chick alpha-2 type 1 collagen gene;" Journal of Biological Chemistry, Vol. 256, No. 21; 1981, pages 11251-11258, XP002270942	
	AN		
	AO		
EXAMINER SIGNATURE:		DATE CONSIDERED:	
<p><small>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴for Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.</small></p> <p><small>The collection of information is required by 37 CFR 1.197 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.</small></p> <p><small>If you need assistance in completing this form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.</small></p>			